

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT
LITIGATION

No. 04-MD-01592

**APPENDIX TO PLAINTIFFS' SUPPLEMENTAL MEMORANDUM
ADDRESSING THE FIRST AMENDMENT IMPLICATIONS OF THE
COURT'S JUNE 23, 2004 PROTECTIVE ORDER**

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UNITED STATES DISTRICT COURT
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IN RE COLUMBIA UNIVERSITY PATENT
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No. 04-MD-01592

DECLARATION OF CARLA M. LEVY

I, Carla M. Levy, declare as follows:

1. I am an attorney licensed to practice in the Commonwealth of Massachusetts. I am associated with the law firm of Foley Hoag LLP in Boston, Massachusetts, Counsel for Biogen Idec MA Inc. and Genzyme Corporation. I base this declaration on my personal knowledge unless otherwise stated.

2. Attached at Tab 1 is a true and correct copy of an excerpt of the transcript of the hearing in Biogen, Inc. et al. v. Columbia University, CA 03-11329 (D. Mass.), which took place in Boston, Massachusetts on June 22, 2004.

3. Attached at Tab 2 are true and correct copies of the following articles: Gary Stix, Working the System II: Corporate Greed No Longer Remains the Sole Domain of the Corporation, Scientific American, March 2004; Eliot Marshall, Depth Charges Aimed at Columbia's "Submarine Patent," Science, July 2003; Naomi Aoki, Biotech Firms Sue Columbia

University, Boston Globe, July 16, 2003; and Andrew Pollack, 3 More Biotech Firms File Suit Against Columbia Over Patent, New York Times, July 16, 2003.

4. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: July 16, 2004

_____/s/ Carla M. Levy
Carla M. Levy

Tab 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BIOGEN, INC., ET AL)	CA 03-11329
)	Boston, MA
v.)	June 22, 2004
)	
COLUMBIA UNIVERSITY, ET AL)	

BEFORE THE HONORABLE MARK L. WOLF
UNITED STATES DISTRICT JUDGE

APPEARANCES:

(As previously noted.)

JUDITH A. TWOMEY, RPR
Official Court Reporter
One Courthouse Way
Courtroom 10~Room 5200
Boston, MA 02210
(617)946-2577

1 MR. GINDLER: That's correct.

2 THE COURT: It doesn't say that Columbia has to.

3 MR. GINDLER: That's correct.

4 THE COURT: So if -- I mean, if Columbia
5 published all of this in the New York Times and then you
6 came in and ordered me, you know, asked me to order the
7 -- not to let inside counsel read it --

8 MR. GINDLER: That would be a bad day for me in
9 court.

10 THE COURT: But that -- I mean, obviously,
11 that's an exaggerated example, but it's not -- I think
12 you're right, it should be analyzed in terms of waiver,
13 but that's why I put it in terms of whether Columbia
14 treats this information -- and you should describe for me
15 with a little more precision what this information is --
16 as a trade secret or, if it doesn't quite rise to a trade
17 secret status, as confidential information deserving a
18 protection. Because, you know, if you told Immunex and
19 when you told Immunex you said, you know, we're giving
20 this stuff to our licensees, you know, I wonder whether
21 that's more like publishing it in the New York Times.
22 You've given it to the, you know, the heart of the
23 information to the relevant universe.

24 On the other hand, if it's distinguishable, it's
25 not like publishing it in the New York Times, and you do

1 show me that you've done things to maintain the
2 confidentiality of something particular that you're
3 concerned about, maybe -- well, then I might be more
4 inclined to do something.

5 MR. GINDLER: This is not a case, though, of
6 everybody having the same thing. And that's an important
7 distinction. So we're not claiming that we have to have
8 attorneys' eyes only or sealing of anything which we gave
9 to Immunex, because we gave it to them. And if they gave
10 it to somebody else, that was our decision to give it to
11 them and we, in effect, chose not to keep that
12 confidential.

13 THE COURT: So that's the claims as of when,
14 2002?

15 MR. GINDLER: It's what we gave to Immunex,
16 which I think happened in May of 2002. I don't have a
17 copy of exactly what we gave to them, but we've never
18 asserted that that's improper. Okay? What is improper
19 and what causes us concern is everything else the Patent
20 Office improperly released. And there was no contention
21 that the other parts of the file history, other amended
22 claims, other argument, other things that Columbia did,
23 should have gotten out. If the Patent Office followed
24 proper procedure, it would not be in the hands of anyone
25 else. But now it's in the hands of quite a few people,

1 and now it's in the court file.

2 You asked the question of is it a trade secret?

3 And I think the answer is not exactly in the way that we
4 would think about trade secrets under the Uniform Trade
5 Secret Act, because patent applications and trade secrets
6 can sometimes overlap and sometimes not. And so I think
7 it's clearer to talk about this in terms of
8 confidentiality, protected by law, and established by
9 law. But I think knowledge of trade secret is not
10 exactly correct. One could use that term.

11 THE COURT: I said trade secret or, if it
12 doesn't quite rise to that level, something confidential.

13 MR. GINDLER: So I think that's a fairer way of
14 describing it, it's just confidential. I think part of
15 the reason it's fairer is because you can waive in almost
16 a subject matter sort of way trade secret protection,
17 just as you can waive lots of protections. But this is
18 entirely established by statute, with exceptions
19 established by statute as to who gets to see it and who
20 doesn't.

21 THE COURT: I know, but I don't think you're
22 contending there's a private right of action under the
23 statute.

24 MR. GINDLER: And we have not attempted to
25 bring such a claim. We're not bringing any causes of

Tab 2

Working the System II

Corporate greed no longer remains the sole domain of the corporation By GARY STIX

Last month this column detailed how a recent lawsuit charged biotech giant Genentech with attempting to retain rights to a technology for more than a decade beyond the original patent's expiration date. These days, however, this type of behavior is by no means confined

to the corporate sector. As university patenting has increased dramatically in the years since the Bayh-Dole Act of 1980, the law that encouraged such activity, academic institutions have taken a lesson or three from the corporations whose convoluted tactics keep a white-knuckled lock around valuable patents. Among the ivory tower set, Columbia University, that august Ivy League institution that is now marking its 250th anniversary, may be lighting the way for other centers of learning.

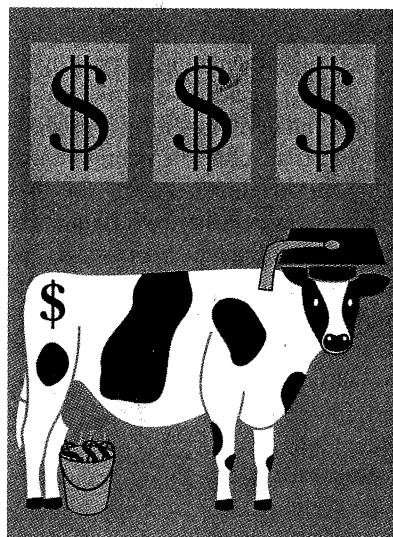
A parade of biotech heavyweights—among them Amgen, Biogen, Genzyme and, yes, Genentech—filed suits against Columbia last year for allegedly trying to prolong for an additional 17 years what is said to be one of the most lucrative university patent estates ever. Three biotech patents that expired in 2000 brought the academic institution almost \$300 million in royalties and licensing fees during their lifetime. But Columbia received another patent in 2002 on what the various plaintiffs claim is essentially the same technology covered by those that had expired: a method for inserting human genes into hamster cells to identify cells that will produce large volumes of proteins from those genes. And Columbia, which maintains that the new patent covers a different invention, has already notified previous licensees of its intention to keep the cash flowing. But the plaintiffs

in the various suits want the new patent invalidated.

The patent fight demonstrates that a university is as able as any corporation to do anything in its power to continue milking an intellectual-property cash cow. In devising a strategy to maintain a grip on its blockbuster, Columbia may even be able to teach corporate patent holders a few lessons. It enlisted Columbia alumnus Judd Gregg, now a senator from New Hampshire, to stick a provision in a few bills in 2000 that would extend its patent protection for 15 months. Moreover, even while the school begged legislators for an extension, it was secretly pursuing new patents, a fact never revealed to Congress, according to the complaint filed by Foley Hoag, the Boston-based law firm retained by Biogen, Genzyme and Baxter Healthcare. The patent in dispute “surfaced” in 2002 (another one is still pending) after the unsuccessful lobbying effort was completed.

This classic “submarine” patenting strategy will probably be remembered for years to come. The funding for the research for the original three patents came from the National Institutes of Health. At the time, Columbia had to obtain title to the invention from the NIH. But in doing so, the NIH stipulated that the university “shall include adequate safeguards against unreasonable royalties and repressive practices.”

The Columbia imbroglio illustrates that at least for universities, the size of revenues expected from patents does matter. The era of university patenting has led to many fruitful collaborations in which schools license their discoveries to industry. Often university patents receive only modest royalties or fees. But Columbia's patents were different. The almost \$100 million they garnered in 1999—a large chunk of the money came toward the end of the patents' term—reportedly constituted nearly 25 percent of the university's research budget. The Columbia patents go to prove that when the stakes are high enough, an institution of “higher” learning can get down and connive with the best of them. ■



NEWS OF THE WEEK

tion, the Royal Society for the Protection of Birds, and from the Green Alliance pressure group. Biologists, sociologists, and ethicists from numerous universities also participated.

Sue Mayer of the genetic technology watchdog GeneWatch UK commended the review for bringing “the issue of uncertainty to the fore.” Uncertainties include ways to

detect any potential harm to human health and the lack of accurate predictions of environmental impacts. However, “the biggest concern,” in her view, is that the report plays down some issues, such as differences between genetic modification and traditional breeding. Others disagree. “The risks associated with GM in terms of food safety and the

creation of so-called superweeds are minimal,” says Jim Smith, a GM food expert and spokesperson for London’s Royal Society, although he acknowledges that a number of questions remain about how GM technology might affect wild plants and animals.

—JOHN PICKRELL

John Pickrell is a science reporter based in London, U.K.

INTELLECTUAL PROPERTY

Depth Charges Aimed at Columbia’s ‘Submarine Patent’

In 1983, Columbia University secured a fundamental biotechnology patent that has netted hundreds of millions of dollars. The patent has been such a money spinner that the university couldn’t bear to see it expire, so after trying unsuccessfully to get Congress to extend its life, Columbia persuaded the U.S. Patent and Trademark Office to issue a second patent last year on the same invention. That, at least, is how five companies see it. They have blitzed the university

While it was in force, Genentech of South San Francisco estimates that it paid Columbia royalties of more than \$70 million. Biogen of Cambridge, Massachusetts, estimates it paid \$35 million; Genzyme, also of Cambridge, paid almost \$25 million. The total amount paid by about 30 companies, according to a complaint by Biogen and others, is in the “hundreds of millions of dollars.”

Last fall, Columbia obtained a new, 17-year U.S. patent (6,455,275) using claims based on Axel’s original 1980 research. When Columbia began asking biotech companies for new payments this year,

in Los Angeles, respectively.

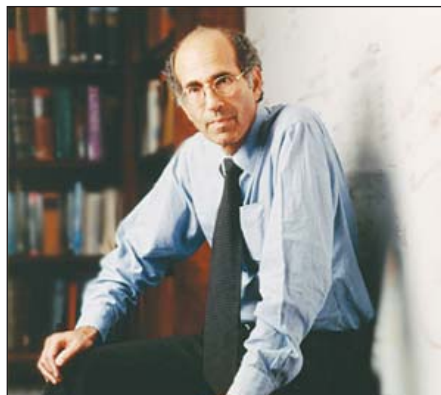
Genzyme’s legal counsel, Thomas DesRosier, argues that the university “pulled a bait and switch” on the patent office, using legal gambits to keep alive a patent on a discovery that is “substantially the same” as the one whose patent died in 2000. The Boston complaint calls the result a “submarine patent,” because it lay dormant for years but burst on a mature industry last fall with new royalty demands. It states that Columbia used “dilatatory tactics” to win the new patent and charges that it previously waged a “widely criticized campaign” in Congress to boost the life of the Axel discovery. Senator Judd Gregg (R-NH), a Columbia alumnus, tried to amend a bill in 2000 to extend the patent’s life by 15 months, but the proposal died amid controversy.

In response to Genentech’s suit, the university wrote that the new patent is “valid and enforceable.” University senior executive vice president Robert Kasdin declines to discuss the case in detail, saying only that “the U.S. Patent and Trademark Office reviewed a patent application filed by us in 1995 and concluded that it reflected a new invention. ... We believe that their conclusion is sound.” The biotech firms are waging legal warfare, an official says, because they “just don’t want to pay” the royalties they owe.

The differences between key parts of Columbia’s 1983 and 2002 patents may appear at first glance to be “more semantic than substantive,” says independent patent attorney Richard Osman of Hillsborough, California. But he warns, “It is imperative to consider the significance of every word of each claim ... before jumping to any conclusions.” It won’t be an easy case for the plaintiffs to make, says Osman: They “must convince the judge or jury that the patent office made a mistake.”

Like others trying to stake out intellectual property rights in the fiercely competitive biotech world, Columbia is learning that an aggressive strategy can bring in lucrative patents—and some blockbuster legal bills.

—ELIOT MARSHALL

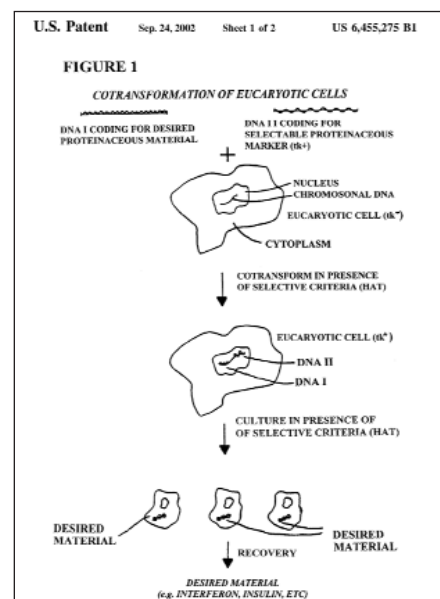


Renewable resource. Richard Axel’s 1980 research netted Columbia University similar patents in 1983 and 2002.

with simultaneous lawsuits in three federal courts. University officials reject the allegations, saying they are just trying to collect on a valid new patent.

The legal jousting centers on a technique for inserting genes into a cell, invented in 1980 by Columbia biologist Richard Axel with colleagues Michael Wigler and Saul Silverstein. Based on their research, the university won a U.S. patent (number 4,399,216) for a “cotransformation” process that inserts two pieces of DNA, one of which expresses the desired protein and the other a “marker” protein that can be used to identify which cells have taken up the DNA. The technique, which makes it simpler to select the transformed cells before growing them in quantity, has become a mainstay of research and commercial production.

The original patent expired in 2000.



they rebelled. Biogen joined with two other firms in Massachusetts—Genzyme and the Abbott Bioresearch Center—to sue the university last week for what they describe as “an illegitimate effort to extend its patent monopoly” on the Axel invention. Filed in federal court in Boston on 15 July, this complaint asks that the patent be declared invalid because it was issued in error. The complaint also seeks legal costs. It echoes complaints filed by Genentech and Amgen of Thousand Oaks, California, on 15 April in San Francisco and on 18 June

CREDITS: (LEFT TO RIGHT) COLUMBIA UNIVERSITY; U.S. PATENT AND TRADEMARK OFFICE



THIS STORY HAS BEEN FORMATTED FOR EASY PRINTING

Biotech firms sue Columbia University

3 companies operating in Mass. accuse school of illegally extending patent

By Naomi Aoki, Globe Staff, 7/16/2003

Three years after the expiration of one of Columbia University's most lucrative patents, a growing number of biotechnology firms are suing the Ivy League school, accusing it of tricking the patent office into issuing a new patent for the same old invention so it can continue to collect hundreds of millions of dollars in royalties.

Biogen Inc., Genzyme Corp., and Abbott Laboratories, three large drug makers operating in Massachusetts, filed suit against Columbia yesterday in federal court in Boston. Echoing legal actions in recent months by California biotech titans Amgen Inc. and Genentech Inc., the civil suit alleges Columbia is illegally extending its monopoly over a process used in making proteins that treat a wide range of diseases from cancer to rheumatoid arthritis.

"There's no question: The invention was a major contribution to the biotech industry," said Tom Bucknum, Biogen's general counsel. "Columbia was amply rewarded over the life of the patent. But time's up. Let's play fair. It now belongs in the public domain."

Over the 17-year life of the patent, Columbia collected nearly \$300 million from more than 30 biotech companies. Genentech alone paid more than \$70 million in licensing fees and royalties, Biogen paid \$35 million, and Genzyme paid \$25 million, according to the lawsuits. And the patent only became more valuable with time, as a growing number of biotech drugs reached the market.

With the prospect of its expiration looming, Columbia turned to Congress in the summer of 2000 in a failed bid to win an extension of the patent. Behind the scenes, it was seeking additional patents, and in September 2002 it won a new patent and another 17 years of protection. Under the terms of the licensing agreements, the university told companies, they were obligated to continue paying royalties.

As of late yesterday, Columbia had not been served with the lawsuits filed by Amgen, Biogen, Genzyme, and Abbott, and therefore, declined to comment on them. Robert Kasdin, a senior executive vice president at Columbia, said the patent office carefully reviewed the university's applications and Columbia believes it rightly determined that the claims in the latest patent are valid.

Yesterday, Kasdin would only respond to the Genentech suit, the first filed. "Columbia will aggressively protect its intellectual property from Genentech's claims," he said. "The revenue

Columbia receives from licensing is invested in new research that leads to drugs that help the ill and technology that makes the economy more productive."

The lawsuits underscore the growing importance of patents to academic institutions that stand to profit from them. Universities are aggressively licensing discoveries by their physicians and researchers to biotech and pharmaceutical companies, and increasingly are relying on those royalty streams to fund their research budgets. In 1999, the year before Columbia's original patent expired, it generated nearly \$100 million. The money accounted for nearly a fourth of the university's research budget.

"The irony is that this is what industry does," said Jonathan Moreno, director of the University of Virginia's Center for Biomedical Ethics. "But we're going to see more of it. Universities have become a major player in developing technologies, and unless that changes, they are going to play by the same rules everyone else does."

The patents at the heart of the lawsuit are based on research by Richard Axel, a professor at Columbia, during the 1970s. Supported by federal grants, Axel and two colleagues created a way to splice bits of DNA into living cells to produce human proteins.

Considered seminal to the field, the technique is used to produce many of today's best-selling biotech drugs, including: Amgen's Epogen, a genetically engineered version of a human protein that stimulates the production of red blood cells (it generated \$2.3 billion in sales last year); Biogen's multiple-sclerosis drug Avonex (it topped \$1 billion in sales last year); Genzyme's Cerezyme to treat a rare genetic disorder known as Gaucher disease (it topped \$600 million in sales last year); and Abbott's Humira, a rheumatoid arthritis drug approved by regulators early this year (it is expected to reach more than \$1 billion in annual sales).

Columbia submitted the invention to the patent office in 1980, winning its first patent on Axel's research three years later. It later won a second and third patent based on the same research, both of which expired in August 2000 along with the original patent. In September, the patent office issued a fourth patent based on the same research described in the first patent, this time extending Columbia's monopoly over the technology until 2019.

The Massachusetts-based suit states that Columbia filed numerous applications in a move to keep the claims alive but delay issuance of an actual patent to get as much protection as possible. In fact, the application that resulted in the fourth patent was filed one day before changes in patent law would have made it impossible for Columbia to use a new but related patent to win an extra 17 years of protection.

The suit also alleges Columbia misled the patent office by withholding relevant information about published research and earlier patent applications. For example, the suit states, Columbia's lawyers neglected to tell the patent officer who ultimately approved the claims in the fourth patent that another examiner had already rejected those claims as being too similar to those covered by the earlier patents. According to the suit, Columbia told Congress one thing in lobbying for an extension and the patent office another in lobbying for a new patent.

"This isn't new: It's technology from the 1970s," said Donald Ware, a litigator with Boston law firm Foley Hoag and lead counsel on the suit filed by the three Massachusetts firms. "It's over the top. It goes way beyond what I've ever seen."

The newest patent appears to cover the same or substantially similar ground as the earlier patents, said attorneys who reviewed the patents but are not involved in the case. Nonetheless, the lawsuit is far from an open-and-shut case.

"Columbia has made so much money on this patent," said Kathleen Madden Williams, cochair of the patent and biomedical practices at Boston law firm Palmer & Dodge. "It only stands to reason they are going to be as creative as they can be in extending the life of those royalties. Ultimately, it becomes a question for the court to decide."

Naomi Aoki can be reached at <mailto:%20naoki@globe.com>.

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July 16, 2003

3 More Biotech Firms File Suit Against Columbia Over Patent

By ANDREW POLLACK

Columbia University is coming under increasing legal attack from biotechnology companies, which accuse it of illegally trying to extend the life of a patent that has brought the institution hundreds of millions in revenue.

Three companies — Biogen, Genzyme and a subsidiary of Abbott Laboratories — joined to sue Columbia yesterday in United States District Court in Boston. The lawsuit follows one filed in Los Angeles last month by Amgen, the nation's largest biotechnology company, and another filed in San Francisco in April by Genentech, the second largest.

The suits say Columbia abused the patent system by obtaining a new patent covering the same invention that an expired patent had covered. The suits seek to invalidate the new patent and establish that the companies do not owe any more money to Columbia.

"We've paid them hundreds of millions of dollars for that invention," said Thomas J. DesRosier, general counsel of Genzyme, a biotechnology company in Cambridge, Mass. He was referring to payments by the industry as a whole. "Under our patent laws we don't think it's appropriate that we have to pay them again."

Robert Kasdin, senior executive vice president at Columbia, said the university had not seen the latest lawsuit and could not comment on it. But in general, he said, the university denies the charge and would not have received the new patent unless the United States Patent and Trademark Office decided that it contained new intellectual property.

In the late 1970's, Columbia scientists, led by Richard Axel, developed a technique useful for genetically engineering animal cells to make them produce biotech drugs like interferon, which is used to treat multiple sclerosis. The first patent, issued in 1983, was licensed by numerous companies and became one of the most lucrative ever held by a university, earning royalty payments of about \$100 million a year in its final years. Columbia used the royalties to support university research.

The patent expired in August 2000. Before it did, Columbia tried to get Congress to extend the patent for 14 to 18 months. But after the biotechnology industry objected, the effort failed. The industry thought that was the end of the matter.

But the university had also applied for additional patents, a technique commonly used by businesses. One application, filed in 1995, led to a patent issued last September. The university is now saying that companies must pay royalties on the new patent, which will last for 17 years.

Biotech drugs are proteins that are commonly produced by putting the gene for the protein into Chinese hamster ovary cells, which then churn out the protein. The Columbia scientists developed a method to

determine which animal cells take up the gene for the drug.